

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 1322-035 PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2005/018631	International filing date (<i>day/month/year</i>) 23 May 2005 (23.05.2005)	Priority date (<i>day/month/year</i>) 21 May 2004 (21.05.2004)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ACCU-BREAK PHARMACEUTICALS, INC.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Date of issuance of this report 21 November 2006 (21.11.2006)</p> <hr/> <p>Authorized officer</p> <p style="text-align: center; font-weight: bold;">Yolaine Cussac</p> <p>e-mail: pt11@wipo.int</p>
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 05 OCT 2005

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To:
JAMES V. COSTIGAN
HEDMAN & COSTIGAN, P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

03 OCT 2005

Applicant's or agent's file reference

1322-035 PCT

Date of mailing
(day/month/year)

FOR FURTHER ACTION

See paragraph 2 below

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US05/18631

23 May 2005 (23.05.2005)

21 May 2004 (21.05.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 9/44 and US Cl.: 424/467

Applicant

SOLAPHARM, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Eric Silverman, PhD

Telephone No. 571-272-1600

Janice Ford
for

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/18631

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/18631

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☐ paid additional fees
 - ☐ paid additional fees under protest
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-26 and 33

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US05/18631

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>13,14 and 16-20</u>	YES
	Claims <u>1-3, 4-12, 15, 21-26, 33</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-26, 33</u>	NO
Industrial applicability (IA)	Claims <u>1-26, 33</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3, 4-12, 15, 21-26, and 33 lack novelty under PCT Article 33(2) as being anticipated by Shah et al. Shah discloses a segmented tablet with two or more segments. The tablet may be broken into pieces and then administered.

Claims 23-25 lack novelty under PCT Article 33(2) as being anticipated by Urban et al. Urban discloses a device for breaking tablets. Said device is disclosed to be useful for breaking tablets in order to allow a subject to administer a reduced dose of the tablet.

Claims 13-14 and 16 lack an inventive step under PCT Article 33(3) as being obvious over Shah, above in view of Hallerback. Shah does not teach the joining of a multitude of segments into a single tablet wherein there are different dosages in each segment. Hallerback teaches a device that contains a multitude of birth control pills, each pill being a tablet that has a different dosage of medicament. Thus, it is obvious to make the plurality of tablets in Hallerback integral by combining them into one tablet as taught by Shah. Making integral is usually a sufficient reason to combine prior art teachings so that such combination need not be suggested by the art itself.

Claims 17 and 18 lack an inventive step under PCT Article 33(3) as being obvious over Shah in view of Addicks. Shah teaches a segmented tablet, but does not teach such a tablet wherein the tablet comprises warfarin. Addicks teaches tablets that comprise warfarin. Thus, it would be obvious to add warfarin to the tablet of Shah in order to obtain a dosage form for warfarin that has the advantages of Shah's tablet.

Claims 17 and 19 lack an inventive step under PCT Article 33(3) as being obvious over Shah in view of Eberlein. Shah teaches a segmented tablet, but does not teach such a tablet wherein the tablet comprises digoxin. Eberlein teaches tablets that comprise digoxin. Thus, it would be obvious to add digoxin to the tablet of Shah in order to obtain a dosage form for digoxin that has the advantages of Shah's tablet.

Claim 17 and 20 lack an inventive step under PCT Article 33(3) as being obvious over Shah in view of Franz. Shah teaches a segmented tablet, but does not teach such a tablet wherein the tablet comprises levodroxine. Franz teaches tablets that comprise levodroxine. Thus, it would be obvious to add levodroxine to the tablet of Shah in order to obtain a dosage form for levodroxine that has the advantages of Shah's tablet.

Claims 1-26, and 33 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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(PCT Rule 43bis.1)

Date of mailing
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See paragraph 2 below

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International application No.
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1. Statement

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	Claims <u>1-3, 4-12, 15, 21-26, 33</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-26, 33</u>	NO
Industrial applicability (IA)	Claims <u>1-26, 33</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3, 4-12, 15, 21-26, and 33 lack novelty under PCT Article 33(2) as being anticipated by Shah et al. Shah discloses a segmented tablet with two or more segments. The tablet may be broken into pieces and then administered.

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